



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0086]

Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in FDA's Tobacco Product Violations Reporting Form.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850,

[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Potential Tobacco Product Violations Reporting Form--(OMB Control Number 0910-0716)--

Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended section 201 et seq. of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321 et seq.) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. FDA is requesting an extension of OMB approval for the collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

FDA created a Tobacco Call Center (with a toll-free number: 1-877-CTP-1373). Callers are able to report potential violations of the Tobacco Control Act, and FDA will conduct targeted followup investigations based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (e.g., cigarette, smokeless, roll-your-own); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated; and the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form FDA 3779. This form is posted on FDA's Web site. The public and interested stakeholders are also able to report information regarding possible violations of the Tobacco Control Act through

the following methods: Calling the Tobacco Call Center using the Center for Tobacco Products' (CTP) toll-free number; using a fillable Form FDA 3779 found on FDA's Web site; downloading a PDF version of the form to send via email or mail to FDA; requesting a copy of Form FDA 3779 by contacting CTP and sending by mail to FDA; and sending a letter to FDA's CTP. The public and interested stakeholders will also be able to report information regarding possible violations of the Tobacco Control Act in the future using FDA's tobacco violation reporting smartphone application.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity and Form FDA 3779	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act, by telephone, Internet form, mail, smartphone application, or email.	400	2	800	0.25 (15 minutes)	200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that submitting the information (by telephone, Internet, mail, smartphone application, or email) will take 0.25 hours (i.e., 15 minutes) per response. FDA estimates the number of annual respondents to this collection of information will be 400, who will each submit 2 reports by telephone, Internet, mail, smartphone application, or email. This estimate is based on the rate of reporting through Form FDA 3779, reports received from FDA's toll-free telephone number and email address, and FDA experience,. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 200 hours (800 responses x 0.25 hours per response). The total burden hours for this collection have decreased by 50 hours (from 250 to 200) because the number of estimated

respondents decreased from 1,000 to 400, and the annual responses are expected to drop from 1,000 to 800 annually. Based on past submissions to FDA, the number of estimated annual respondents is expected to decrease from 1,000 to 400 and each respondent's number of submissions is expected to increase from 1 to 2 annually. Therefore, the number of responses are expected to decrease from 1,000 to 800 annually (400 respondents x 2 responses).

Dated: February 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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